0585-0017-84

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

JULIO PIMENTEL

SERIAL NO. 09/226,597

FILED: JANUARY 7, 1999

FOR: WEIGHT CONTROL USING AN ANTI-LIPASE ANTIBODY

: EXAMINER: GABEL, G.

: GROUP ART UNIT: 1641

DECLARATION UNDER 37 C.F.R. §1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Now comes Kurt Richardson, Ph.D. who deposes and states that:

1. I received my doctoral degree at North Carolina State University in the field of toxicology/physiology in 1986.

2. I did post doctoral studies in microbiology at the National Center for Toxilogical Research, Jefferson Arkansas, from 1986-87 and have worked for Anitox from 1987 to the present in the field of toxicology/physiology.

3. The Examiner has questioned the reasons for selecting rat as the experimental animal. The rodent is considered the primary animal used in research tests. The rationale for this is that 1) rodents possess a genetic uniformity which reduces the possibility for variation, 2) they have well defined physiological parameters (their physiological responses to foreign agents/compounds are well documented), 3) they are readily available from commercial sources, 4) they are easy to handle and maintain and 5) they have relatively short life spans

which allows the opportunity to study long term effects. In my experience rats are commonly used in immunological-type experiments to test antibody-based products and are an art-recognized model for such research.

The American College of Laboratory Animal Medicine has published a review of and references for several research uses of the rat in studies involving gnotobiology, dental research, embryology and teratology, toxicology, oncology, gerontology, cardiovascular research, immunology, immunogenetics, and infectious disease research. The rat is the second most commonly used animal species in biomedical research and testing. Rats comprise about 21% of all animals used, and when coupled with mice, these two species account for about 88% of all animals used in research and testing.

4. The Examiner has questioned whether animal feed with 30% fat content, as used in Example 3, is representative of standard feeds having lower fat content. Such data is representative and useful for showing that anti-lipase antibodies inhibit weight gain. In biological experiments it is often appropriate to increase the dose of a component in order to produce a clear experimental effect or to reduce the time of the test. In this case rats were used because they have higher body weight than mice, and high fat in the feed gave a clear and significant effect.

In practice, animal feeds contain some percentage of fat, including plants, because the plant cell wall contains lipids.

5. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

6. Further deponent saith not.

Signature

10/24/01
Date

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